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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,165	11/19/2001	Michael Zeppezauer	44011.010700	8263

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,165	ZEPPEZAUER ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. **As set forth previously**, the sequences in the claims must be brought into sequence compliance and identified by SEQ ID NO:. Failure to due so in response to this notice will be held non-responsive.

Additionally, the Sequence Listing filed on 11/04/04, is considered non-compliant and has not been entered into the application for the following reasons:

The Sequence Listing has not been entered because the Statement of Support under 1.821 is not properly signed by a registered attorney or agent, see MPEP 714.01(a) which states:

(b) Amendments and other papers. Amendments and other papers, except for written assertions pursuant to § 1.27(c)(2)(ii) of this part, filed in the application must be signed by:

(1) A registered attorney or agent of record appointed in compliance with § 1.34(b);

(2) A registered attorney or agent not of record who acts in a representative capacity under the provisions of § 1.34(a);

(3) An assignee as provided for under § 3.71(b) of this chapter; or

(4) All of the applicants (§ 1.41(b)) for patent, unless there is an assignee of the entire interest and such assignee has taken action in the application in accordance with § 3.71 of this chapter.

The paper is signed by Rebecca J. Goodwin who appears to be none of the above, as evidenced by the absence of a registration number.

2. A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because an excessive number of corrections and replacement paragraphs have been submitted.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing

all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strikethrough except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strikethrough cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Applicant is advised to see MPEP 608.01(a) regarding the proper format of a specification.

3. Applicant is further invited to amend the claims such that they comprise proper idiomatic English, including proper spelling. Said amendment would facilitate and expedite prosecution.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a peptide comprising an AxKKK motif, classified in Class 530, subclass 330.

II. Claim 1 consisting of the peptide PEPAKSAPAPKKGSKKAVTKAQKKDGKKRKRSEKE, or fragment thereof, classified in Class 530, subclass 326.

III. Claim 1 consisting of the peptide SYSVYVYKVLKQVHPDTGISSKAMGIMNSFVNDIFERIAGE, or fragment thereof, classified in Class 530, subclass 325.

IV. Claim 1 comprising a combination of peptides consisting of: an AxKKK motif, PEPAKSAPAPKKGSKKAVTKAQKKDGKKRKRSEKE, and SYSVYVYKVLKQVHPDTGISSKAMGIMNSFVNDIFERIAGE, or fragments thereof classified in Class 530, subclasses 325, 326, and 330.

V. Claims 3-7, drawn to a method of improving diagnosis of autoimmun diseases employing peptides, classified Class 435, subclass 6.

VI. Claims 8 and 9, drawn to a method for therapy of autoimmun diseases employing peptides, classified Class 424, subclass 185.1.

VII. Claim 10, drawn to a method for the production of the antiidiotypic antibody, classified Class 424, subclass 185.1

VIII. Claims 11 and 12, drawn to a method of improving diagnosis of autoimmun diseases employing an antiidiotypic antibody, classified Class 424, subclass 184.1

IX. Claims 13 and 14, drawn to a method for therapy of autoimmun diseases employing an antiidiotypic antibody, classified in class 435, subclass 131.1.

5. Inventions V-IX, are different methods. Said methods comprise different reagents/components, in particular, unrelated peptides comprising different motifs (Groups V-VI) or antiidiotypic antibodies (Groups VII-IX), or said methods comprise different method steps and outcomes, e.g., diagnosis (Groups V and VIII) versus treating (Groups VI and IX) autoimmun diseases.

6. Inventions I-IV and V-VI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides of the product claims can be used for the generation of antibodies or the activation of T cells.

7. Inventions I-IV are different products. Said products comprise different peptide motifs, i.e., they comprise different proteins with different biological activities.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. This application also contains inventions drawn to patentably distinct species. Should Applicant elect Group IV, Applicant is further required under 35 U.S.C. 121 to:

A) elect a specific combination of specific peptides, and
B) list all Claims readable thereon including those subsequently added. Currently Claim 1 is generic.

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different peptide motifs comprise different proteins with different biological activities. Therefore, the species are independent and patentable over one another.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP ' 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Applicant is advised, however, that to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all elected product claims are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims

that are not commensurate in scope with an allowed product claim will not be rejoined. See A Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. ' 103(b),@ 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

14. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/29/05

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600